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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, WARNER CHILCOTT COMPANY, INC., WARNER CHILCOTT (US), LLC and MAYNE PHARMA INTERNATIONAL PTY. LTD.,	
Plaintiffs,	CIVIL ACTION NO. 09-1233 (WJM)
v.	
IMPAX LABORATORIES, INC.,	
Defendant.	

ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant, Impax Laboratories, Inc. (hereinafter "Impax"), by its attorneys, answers the Complaint herein as follows:

NATURE OF ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

ANSWER: Impax admits the allegations contained in paragraph 1 of the Complaint.

THE PARTIES

2. Plaintiff Warner Chilcott Laboratories Ireland Limited ("WCLI") is a company organized and existing under the laws of the Republic of Ireland, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 2 of the Complaint and therefore denies those allegations.

3. Plaintiff Warner Chilcott Company, Inc. ("WCCI") is a company established under the laws of the Commonwealth of Puerto Rico, having offices at Union St., Road 195, Km 1.1, Fajardo, Puerto Rico.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3 of the Complaint and therefore denies those allegations.

4. Plaintiff Warner Chilcott (US), LLC ("WCUS") is a limited liability company established under the laws of the state of Delaware with offices at 100 Enterprise Drive, Rockaway, NJ 07866. WCLI, WCCI, and WCUS hereinafter are referred to collectively as "Warner Chilcott".

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 4 of the Complaint and therefore denies those allegations.

5. Plaintiff Mayne Pharma International Pty. Ltd. ("Mayne") is a corporation organized and existing under the laws of Australia, having a principal place of business at Level 21-390 St. Kilda Road, Melbourne, Australia 3004.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 5 of the Complaint and therefore denies those allegations.

6. Mayne was formerly known as F. H. Faulding & Co., Ltd.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 6 of the Complaint and therefore denies those allegations.

7. On information and belief, Defendant Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

ANSWER: Impax admits the allegations contained in paragraph 7 of the Complaint

JURISDICTION AND VENUE

8. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Impax admits that this action purports to arise under the Patent Laws of the United States and the Food and Drug Laws of the United States, and Impax admits

the allegations in the second sentence of paragraph 8. Impax denies the remaining allegations of paragraph 8.

9. Impax sells various products and does business throughout the United States, including in this judicial district. Impax has maintained continuous and systematic contacts in New Jersey, and has previously consented to personal jurisdiction in this district including in a pending proceeding that involves the same patent that is at issue here: *Warner Chilcott Laboratories Ireland Limited et al. v. Impax Laboratories, Inc. et al.*, Civ. Docket No. 2:08-cv-06304-WJM-MF.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent that an answer is required, Impax does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Impax admits that it previously consented to personal jurisdiction in this district for the limited purpose of the currently pending proceeding involving the same patent that is at issue here: *Warner Chilcott Laboratories Ireland Limited et al. v. Impax Laboratories, Inc. et al.*, Civ. Docket No. 2:08-cv-06304-WJM-MF. Impax denies the remaining allegations of paragraph 9.

10. On information and belief, this Court has personal jurisdiction over Impax by virtue of, *inter alia*, the above-mentioned facts.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 10 of the Complaint and therefore denies those allegations.

11. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), and 28 U.S.C. § 1400(b).

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent that an answer is required, Impax does not contest venue in this judicial district for the limited purpose of this action only. Impax denies the remaining allegations of paragraph 11.

CLAIM FOR RELIEF -- PATENT INFRINGEMENT

Plaintiffs' NDA and U.S. Patent No. 6,958,161

12. Mayne is the holder of New Drug Application ("NDA") No. 50-795 which relates to delayed-release tablets containing 75 mg base, 100 mg base and 150 mg base of doxycycline hyclate.

ANSWER: Upon information and belief, Impax admits the allegations of paragraph 12

13. The United States Food and Drug Administration ("FDA") has approved the use of the tablets described in NDA No. 50-795 for the treatment of a variety of bacterial infections as described in the product labeling. The 75 mg base and 100 mg base tablets were approved by the FDA on or about May 6, 2005, and the 150 mg base tablets were approved on or about June 20, 2008. These tablets are prescribed and sold in the United States under the trademark Doryx®.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 13 of the Complaint and therefore denies those allegations.

14. Mayne is the owner of United States Patent No. 6,958,161 ("the '161 Patent," copy attached as Exhibit A), entitled "Modified Release Coated Drug Preparation."

ANSWER: Impax admits that the '161 patent is entitled "Modified Release Coated Drug Preparation" and that a copy of the '161 patent was attached to the Complaint as Exhibit A.

Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 14 of the Complaint.

15. The '161 Patent was duly and legally issued by the United States Patent and Trademark Office on October 25, 2005. The '161 Patent claims, *inter alia*, modified release preparations of doxycycline hyclate, and is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") as covering Doryx Delayed-Release Tablets ("Doryx®").

ANSWER: To the extent that paragraph 15 of the Complaint states conclusions of law, Impax states that no response is required. Impax admits that the '161 patent was issued by the United States Patent and Trademark Office on October 25, 2005 and is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as "the Orange Book") as covering Doryx Delayed-Release Tablets ("Doryx®"). Impax denies that the '161 patent was "duly and legally" issued and denies the remaining allegations of paragraph 15 of the Complaint.

16. The '161 Patent originally was assigned by the inventors to F. H. Faulding & Co. Limited, and subsequently assigned to Mayne.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of the Complaint and therefore denies those allegations.

17. Warner Chilcott has exclusive rights to market and sell product covered by the '161 Patent in the United States, including Doryx®.

ANSWER: Impax lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of the Complaint and therefore denies those allegations.

Impax's Prior Infringement and Prior ANDA No. 90-505

18. On information and belief, prior to December 10, 2008, Impax submitted to the FDA a separate ANDA, ANDA No. 90-505, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg base, which are covered by one or more claims of the '161 Patent.

ANSWER: To the extent that paragraph 18 of the Complaint states conclusions of law, Impax states that no response is required. Impax admits that prior to December 10, 2008 it submitted to the FDA an Abbreviated New Drug Application ("ANDA") No. 90-505 seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 75 mg and 100 mg. Impax denies the remaining allegations of paragraph 18.

Impax's Infringement and ANDA No. 91-132

19. On information and belief, on December 19, 2008, Impax submitted to the FDA an Abbreviated New Drug Application ("ANDA") No. 91-132 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 150 mg base ("Impax's Proposed Drug Product"), which is covered by one or more claims of the '161 Patent.

ANSWER: To the extent that paragraph 19 of the Complaint states conclusions of law, Impax states that no response is required. Impax admits that it submitted to the FDA an

Abbreviated New Drug Application ("ANDA") No. 91-132 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic Doxycycline Hyclate Delayed-Release Tablets 150 mg base ("Impax's Proposed Drug Product"). Impax denies the remaining allegations of paragraph 19.

20. On information and belief, Impax submitted ANDA No. 91-132 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Impax's Proposed Drug Product before the expiration of the '161 Patent.

ANSWER: Impax admits it submitted ANDA No. 91-132 to the FDA for the purpose of obtaining approved to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Impax's Proposed Drug Product before the expiration of the '161 patent.

21. On information and belief, Impax made, and included in ANDA No. 91-132, a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in its opinion and to the best of its knowledge, the '161 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale, of Impax's Proposed Drug Product.

ANSWER: Impax admits that it included in ANDA 91-132 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that in its opinion and to the best of its knowledge, the '161 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of Impax's Proposed Drug Product.

22. By filing ANDA No. 91-132 under 21 U.S.C. § 355(j), for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of Impax's Proposed Drug Product before the expiration of the '161 Patent, and Paragraph IV Certification, Impax has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, the commercial manufacture, use, offer for sale, sale and/or importation of Impax's Proposed Drug Product for

which Impax seeks approval in ANDA No. 91-132 will also infringe one or more claims of the '161 Patent.

ANSWER: Impax denies the allegations of paragraph 22 of the Complaint.

23. Impax's Proposed Drug Product, if approved, will be administered to human patients for the treatment of infections, which administration constitutes direct infringement of the '161 Patent. This will occur at Impax's active behest, and with its specific intent, knowledge and encouragement. On information and belief, Impax will actively induce, encourage, aid and abet this administration with the knowledge that it is in contravention of Plaintiffs' rights under the '161 Patent.

ANSWER: Impax denies the allegations of paragraph 23 of the Complaint.

24. On information and belief, Impax did not allege in its Paragraph IV Certification that the '161 Patent is invalid under any of 35 U.S.C. § 101 *et seq*.

ANSWER: Impax denies the allegations of paragraph 24 of the Complaint.

25. On information and belief, Impax did not allege in its Paragraph IV Certification that the '161 Patent is unenforceable.

ANSWER: Impax denies the allegations of paragraph 25 of the Complaint.

26. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 91-132 relating to Impax's Proposed Drug Product be a date which is not earlier than the date of expiration of the '161 Patent or any later date of exclusivity to which Plaintiffs are or become entitled. Furthermore, Plaintiffs are entitled to an award of damages for any commercial sale or use of Impax's Proposed Drug Product, and any act committed by Impax with respect to the subject

matter claimed in the '161 Patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

ANSWER: Impax denies the allegations of paragraph 26 of the Complaint.

27. On information and belief, Impax lacked a good faith basis for its Paragraph IV Certification when ANDA No. 91-132 was filed. Impax's ANDA No. 91-132 and Paragraph IV Certification is a wholly unjustified infringement of the '161 Patent.

ANSWER: Impax denies the allegations of paragraph 27 of the Complaint.

28. Impax has violated its duty of due care to avoid the known patent rights of the '161 Patent.

ANSWER: Impax denies the allegations of paragraph 28 of the Complaint.

29. This is an exceptional case and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Impax denies the allegations of paragraph 29 of the Complaint.

30. Impax denies each and every other allegation of the Complaint not expressly admitted above.

FIRST AFFIRMATIVE DEFENSE

31. Upon information and belief, Impax has not infringed any valid and enforceable claim of United States Patent No. 6,958,161 ("the '161 patent")

SECOND AFFIRMATIVE DEFENSE

32. Upon information and belief, Impax alleges that the '161 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the

United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103 and 112.

THIRD AFFIRMATIVE DEFENSE

33. Any claim of infringement of the '161 patent by Impax under the doctrine of equivalents would be limited by prosecution history estoppel.

FOURTH AFFIRMATIVE DEFENSE

34. Any claim of infringement of the '161 patent by Impax under the doctrine of equivalents would be limited by prior art estoppel.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Impax counterclaims against Plaintiffs for declaratory relief and alleges:

35. Subject matter jurisdiction for this counterclaim for declaratory judgment is based upon 28 U.S.C. §§ 1331, 1338, 2201 and 2202 and Rule 13 of the Federal Rules of Civil Procedure. An actual case or controversy exists between Plaintiffs and Impax based upon Plaintiffs having filed this Complaint against Impax.

COUNT I

36. Impax incorporates by reference and re-alleges the allegations contained in paragraphs 31-34 of this Answer.

37. Impax is entitled to a judgment declaring that it has not infringed any valid and enforceable claim of the '161 patent.

COUNT II

38. Impax incorporates by reference and re-alleges the allegations contained in paragraphs 31-34 of this Answer.

39. Impax is entitled to a judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation of the drug product that is the subject of ANDA 91-132 would not infringe any valid claims of the '161 patent.

COUNT III

40. Impax incorporates by reference and re-alleges the allegations contained in paragraphs 31-34 of this Answer.

41. Impax is entitled to a judgment declaring that the '161 patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103 and 112.

WHEREFORE, Impax demands:

A. That the Complaint filed herein be dismissed and that the Plaintiffs have and recover nothing by reason thereof;

B. that United States Patent No. 6,958,161 be declared and adjudged invalid;

C. that it be declared and adjudged that Impax has not and will not directly or indirectly infringe any valid and enforceable claim of United States Patent No. 6,958,161;

D. that this case be adjudged and decreed an exceptional case under 35 U.S.C. §285 and that Impax be entitled to recover reasonable attorneys' fees and costs incurred in this action;

E. that Impax be awarded damages, including punitive damages, for the assertion of a patent which Counterclaim Defendants knew was not infringed by Impax; and

F. such other and further relief as the Court deems just and equitable.

Dated: April 3, 2009

s/ Michael E. Patunas
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